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## **EU-28**

### **Food and Agricultural Import Regulations and Standards - Narrative**

### **FAIRS Country Report**

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**Report Highlights:**

This report provides an overview of EU food and feed legislation currently in force. All sections of the report were updated but special attention should be given to EU's new novel food rules (Section VI) which will become applicable on January 1, 2018. For updates on developments in EU food and feed legislation check the FAS/USEU website [www.usda-eu.org](http://www.usda-eu.org).

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This report was prepared by the Office of Agricultural Affairs, U.S. Mission to the European Union in Brussels, Belgium for U.S. exporters of domestically produced food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. Final approval of any product is subject to the importing country's rules and regulations as interpreted by border officials at the time of product entry.

## Section I. General Food Laws

The European Union (EU) has gradually expanded to become the world's largest multi-nation trading bloc. Since July 1, 2013, the European Union comprises 28 member states with approximately 500 million consumers. EU member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom. Iceland, Montenegro, the Former Yugoslav Republic of Macedonia, Turkey, Albania and Serbia are candidates to join the EU.

All EU Member countries accept the "Community acquis", i.e. the entire body of EU laws and obligations associated with the treaties and international agreements to which the EU is a party. EU Member States share a customs union, a single market in which goods can move freely, a common trade policy and a common agricultural and fisheries policy.

According to a European Commission memo published in December 2012, around 98% of food legislation is harmonized at the EU level. It is important to note that when EU-wide legislation is incomplete or absent, the laws of Member States apply, often resulting in different rules in different Member States. National measures still exist, for example, for certain food contact materials, the addition of nutrients to food and food supplements, maximum levels for vitamins and minerals, and for official control fees. Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete. The FAIRS reports prepared by the Offices of Agricultural Affairs in the EU Member States are excellent sources of information on Member State specific requirements. These reports can be downloaded from the FAS website at <http://gain.fas.usda.gov/Pages/Default.aspx>.

The principle of free movement of goods is set out in the EU Treaties and is directly applicable in all Member States. Mutual recognition applies to products which are not subject to EU harmonized legislation or to aspects of products falling outside of the scope of such legislation. Under the principle of mutual recognition, different national technical rules continue to coexist within the EU's internal market but a product lawfully produced and/or marketed in one Member State should be allowed to be marketed in any other Member State. There is one exception to this principle: certain directives allow Member States to make exceptions e.g. in cases where a country can prove public safety, health or environmental concerns about a product intended for import. [Regulation 764/2008](#), adopted in July 2008, sets out the procedural requirements for denying mutual recognition and defines the rights and obligations of national authorities on the one hand and enterprises on the other. For more information on the concept of mutual recognition see the European Commission website [http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index\\_en.htm](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm).

The EU has followed a dual approach in harmonizing food laws: "horizontal" legislation covering aspects common to all foodstuffs (such as additives, labeling, hygiene, etc.) and "vertical" legislation on specific products (e.g., wine, cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, novel foods, etc.). U.S. exporters should be aware that products may have to comply with several pieces of

legislation. For example, wine labeling rules are set out in specific (vertical) legislation but allergen labeling rules which also apply to wine are set out in the EU's general food labeling (horizontal) regulation.

EU food legislation is characterized by a constant flow of new regulations and directives, amendments to existing legislation and implementation rules. EU laws are translated into the 24 official languages in use in the EU-28 and published in the Official Journal as soon as they are translated. Directives define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). Regulations are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. Consolidated texts, i.e. the consolidation of a basic legal act and subsequent amendments into one text, are available on the European Commission's website but come with a warning that they are not legally binding. When legislation is referenced in this guide, it is implied that all further amendments also apply. Where possible, this guide links directly to the consolidated versions of referenced EU legislation. The Eurlex website (<http://eur-lex.europa.eu/en/index.htm>) provides free access to European Union law.

The EU has developed an integrated “Farm to Fork” approach covering all sectors of the food and feed chain, based on the precautionary principle and including traceability as described in the [Commission Communication on the Precautionary Principle](#). Key elements of this approach include the establishment of a framework regulation laying down the general principles and requirements of EU food law ([Regulation 178/2002](#)); the establishment of the European Food Safety Authority (EFSA) which is an independent body providing scientific advice to the legislators; the development of specific food and feed safety legislation; and, the creation of a framework for harmonized food controls ([Regulation 882/2004](#)). An [EFSA “infographic”](#) explains the difference between “risk assessment” and “risk management”. The regulations on general food law, food and feed controls, food and feed hygiene make up the body of the EU's food safety laws. Revisions of existing EU food regulations or new regulations all apply the principles contained in these framework regulations. For more information see <http://www.usda-eu.org/topics/food-safety/>.

There are three main institutions involved in developing policies and passing legislation that applies throughout the EU: the European Commission, the Council of the European Union and the European Parliament. In principle, the Commission proposes new laws and the Council and European Parliament adopt them under the “Ordinary Legislative Procedure” (ex co-decision). The precautionary principle is often invoked by the EU legislators to the detriment of innovation. Detailed information on the EU procedures can be found in [GAIN report “How the EU works – A guide to EU decision-making”](#).

In May 2015, the European Commission presented its “Better Regulation Package”, a so-called update of its own law-making practices in order to meet EU legislators' and citizens' expectations in terms of impact assessment, transparency, stakeholder consultation and implementation. The “REFIT” program, launched in 2013, evaluates whether existing legislation is still fit for purpose and makes changes where needed. Information on the Better Regulation Package and the REFIT program is available on the European Commission's website [http://ec.europa.eu/smart-regulation/index\\_en.htm](http://ec.europa.eu/smart-regulation/index_en.htm).

The “European Group on Ethics in Science and New Technologies” (EGE) is an independent and multi-

disciplinary advisory body tasked to advise the European Commission on ethical aspects of science and new technologies in preparation of new EU legislation and policies. For more information see the European Political Strategy Centers' website [http://ec.europa.eu/epsc/ege\\_en.htm](http://ec.europa.eu/epsc/ege_en.htm).

EFSA is responsible for providing scientific advice to the legislators on matters related to food safety. EFSA's "Applications Helpdesk" acts as a front office and support desk for applicants who have questions regarding applications in the following scientific areas: animal by-products, decontamination substances, feed additives, food contact materials, food ingredients, food processing, agricultural biotechnology products, nutrition and pesticides. For more information see <http://www.efsa.europa.eu/en/applicationshelpdesk.htm>.

Enforcement of EU food legislation is done by Member State officials. Auditing oversight of Member State performance is done by European Commission officials. The European Commission has the power to initiate legal action in the European Court of Justice against Member States who are not complying with EU Directives and Regulations.

**See our website  
[www.usda-eu.org](http://www.usda-eu.org)  
for updates on EU food laws and policies**

## **Section II. Food Additive Regulations**

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/food-additives/>

The EU's "Package on Food Improvement Agents" includes four Regulations: [Regulation 1331/2008](#) establishing a common authorization procedure for food additives, food enzymes and food flavorings, [Regulation 1332/2008 on food enzymes](#), [Regulation 1333/2008 on food additives](#) and [Regulation 1334/2008 on flavorings](#).

[Regulation 1331/2008](#) establishes a common authorization procedure for food additives, food enzymes and food flavorings based on safety evaluations carried out by the European Food Safety Authority (EFSA). The implementing rules are laid down in Commission [Regulation 234/2011](#), explaining the content of an application and all the data both administrative and technical that have to be submitted to the Commission. The Commission will then request EFSA to verify the suitability of the data. An application consists of a letter, a technical dossier and a summary of the dossier.

### **A. Additives (including colors and sweeteners)**

Additives that are authorized in food and their conditions of use are listed in Annex II to the [Food Additives Regulation 1333/2008](#). The authorized uses of additives are listed according to the category of

food to which they may be added. Annex I to regulation 1333/2008 lists the definitions of 26 different categories of food additives. Only additives included in the EU's positive list are authorized under specific conditions. An important difference from U.S. legislation is that the use of flour bleaching agents chlorine, bromates and peroxides is not allowed in the EU.

Annex III to Regulation 1333/2008 contains a second list of food additives approved for the use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. Specifications for food additives listed in Annexes II and III are laid down in [Commission Regulation 231/2012](#).

Annex IV lists traditional foods for which certain Member States may continue to prohibit the use of certain categories of food additives.

Annex V to Regulation 1333/2008 contains labeling information for six food colors: Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122) and Allura Red AC (E129). Foods containing these colors have to be labeled "may have an adverse effect on activity and attention in children" (see also Section V – Labeling Requirements). The limits for these food colors were lowered by [Commission Regulation 232/2012](#).

An evaluation program set up by [Commission Regulation 257/2010](#) requires a new risk assessment carried out by EFSA for additives which were approved before Food Additives Regulation 1333/2008 entered into force.

The re-evaluation of approved food additives shall be completed by the end of:

- 2015 for food colors (currently listed in Directive 94/36/EC)
- 2015-2016 for preservatives, antioxidants, glutamates, silicon dioxide
- 2018 for all additives other than colors and sweeteners (currently in Directive 95/2/EC)
- 2020 for all sweeteners (currently listed in Directive 94/35/EC)

On October 13, 2015, EFSA published a [list of food additives under re-evaluation](#). Data on usage level and/or concentration data in food and beverages intended for human consumption can be submitted to EFSA until May 31, 2016.

The Commission's [food additives database](#) together with its [user guide](#) provides detailed information on the different food additives allowed in the EU. More information on the use of food additives can be obtained from the European Commission's website at [http://ec.europa.eu/food/safety/food\\_improvement\\_agents/index\\_en.htm](http://ec.europa.eu/food/safety/food_improvement_agents/index_en.htm).

## **B. Flavorings**

[Regulation 1334/2008](#) on flavorings and certain food ingredients with flavoring properties sets specific rules for the use of the term "natural". Annex I of [Regulation 1334/2008](#) establishes a list of substances

that are authorized for use in the EU. The authorized uses of flavoring substances are listed according to the category of food to which they may be added and are also available in an [on-line database](#) allowing consumers, food businesses and food control authorities to verify which flavoring substances are authorized in food.

[Commission Regulation 873/2012](#) concerns transitional measures for other flavorings such as flavorings made from non-food sources.

The procedure for the safety assessment and the authorization of smoke flavorings intended for use in or on foods is established in [Regulation 2065/2003](#). The Union list of authorized smoke flavoring primary products for use as such in or on foods and/or for the production of derived smoke flavorings is established by [Commission implementing Regulation 1321/2013](#).

### C. Enzymes

[Regulation 1332/2008](#) on food enzymes introduced harmonized rules for their scientific evaluation and authorization in the EU and establishes labeling requirements. Specific labeling requirements are set in Articles 10-13 of Regulation 1332/2008.

[Regulation 234/2011](#) on the implementation of the common authorization procedure, last amended by [Commission Implementing Regulation 562/2012](#) regarding specific data required for risk assessment of food enzymes, sets out a deadline of two years starting from September 11, 2011 to submit applications on existing and new enzymes and for industry to provide the information for the risk assessment. However, the initial deadline for submitting applications was extended to 42 months by [Commission Regulation 1056/2012](#), amending Regulation (EC) No 1332/2008.

Until the adoption of an EU positive list of authorized enzymes, the existing national provisions on the marketing of food enzymes will continue to apply.

### D. Processing Aids

Processing aids are subject to Member States national legislation. EU harmonized rules exist only for certain categories of processing aids: a list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in [Council Directive 2009/32/EC](#).

## Section III. Pesticides and Contaminants

### A. PESTICIDES

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/pesticides/>

[European Parliament and Council Regulation 1107/2009](#) sets out rules for the authorization of plant protection products (PPPs). [Commission implementing Regulation 540/2011](#), establishes a list of



approved active substances. Only PPPs containing active substances included in the list may be authorized for use in the EU. Member States can approve PPPs containing the active substances. According to the new Regulation, the EU is divided in three different zones. Once a Member State approves the PPP it can be mutually recognized and thus authorized within the same EU zone as set out in Annex I of the Regulation. The Maximum Residue Levels (MRLs) for substances not on the list will be set at default level of 0.01 mg/kg. The legislation allows exporters to request an "import tolerance" for active substances not yet evaluated or in use in the EU.

Directive 2009/128 on the sustainable use of pesticides is part of the so-called Pesticides Package. For more information see the European Commission website

[http://ec.europa.eu/food/plant/pesticides/sustainable\\_use\\_pesticides/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/index_en.htm).

### **Maximum Residue Limits (MRLs): Regulation 396/2005**

Since September 2008 all MRLs in the EU have been harmonized by [European Parliament and Council Regulation 396/2005](#) on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. MRLs apply to 315 fresh products and to the same products after processing. See the European Commission's website at [http://ec.europa.eu/food/plant/pesticides/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/index_en.htm) for the latest updates.

- Annex I lists the commodities to which MRLs apply.
- Annex II contains existing MRLs that were already harmonized at EU level and replaces the EU's old MRL Directives.
- Annex III lists EU "temporary" MRLs or pesticides for which, before September 1, 2008, MRLs were only set at national level.
- Annex IV lists the substances for which no MRLs are required and so are exempt from tolerance products.
- Annex V will contain the list of pesticides for which a default limit other than 0.01 mg/kg will apply. Pesticide MRLs for processed or composite products are based on the MRLs for the raw agricultural ingredients.
- Annex VI will contain the list of conversion factors of MRLs for processed commodities. This Annex has not been published yet.
- Annex VII contains a list of pesticides used as fumigants for which the Member States are allowed to apply special derogations before the products are placed on the market.

For a list of authorized active substances or pesticide-MRL combinations, see the European Commission's online database at <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>.

### **Import Tolerance**

If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the "Rapporteur Member State" (RMS). The Commission assigns a Member State, if no RMS exists. The RMS reviewed dossiers are evaluated by the European Food Safety Authority before being forwarded to the Commission. Information on import

tolerances is available in [“Pesticide Use and Food Safety” guide](#) published by the European Crop Protection Association. Since September 2, 2008 all MRLs, including import tolerances, apply EU wide.

## Official Controls

Harmonized sampling methods are established for the official control of residues in and on products of plant and animal origin by [Commission Directive 2002/63/EC](#). [Commission Implementing Regulation 2015/595 outlines the latest version of the coordinated multi annual control program of the EU for pesticides residues, which](#) requires Member States to take and analyze samples for product and pesticide residue combinations in food of plant and animal origin. Annex I to the Regulation sets out the pesticide and product combinations to be monitored. Annex II sets out the number of samples that need to be taken for each combination. The Member States must submit results of the sample tests to the EU by 31 August 2017, 2018 and 2019 for samples tested in 2016, 2017 and 2018 respectively. For more information see the European Commission website

[http://ec.europa.eu/food/plant/pesticides/max\\_residue\\_levels/enforcement/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/max_residue_levels/enforcement/index_en.htm).

## B. CONTAMINANTS

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/contaminants/>

### Maximum Levels

EU wide harmonized maximum levels for contaminants are set in the Annex of [Commission Regulation 1881/2006](#). The Annex to Regulation 1881/2006 includes maximum levels for:

- Nitrates in lettuce, spinach and infant food (section 1)
- Mycotoxins (section 2):
  - aflatoxins in nuts, dried fruit, cereals, maize, spices, milk and infant food
  - ochratoxin A in cereals, cereal products, dried vine fruit, roasted coffee, soluble coffee, wine, grape juice, spices, infant food and licorice
  - patulin in fruit juices, spirit drinks, solid apple products, apple juice and infant food
  - deoxynivalenol in cereals, cereal products, maize, pasta and infant food
  - zearelenone in cereals, cereal products, maize, refined maize oil, bread and small bakery wares and infant food
  - fumonisins in maize and maize based products
  - T-2 and HT-2 toxin in cereals and cereal products
  - citrinin in rice/yeast fermented food supplements
- Heavy metals (section 3):
  - lead in milk, baby and infant food, meat, offal, seafood, vegetables, fruit, wine and food supplements
  - cadmium in meat, fish and seafood, cereals, soybeans, vegetables, fruit, fungi and food supplements, baby formula and infant food, cereals and soybeans, cocoa
  - mercury in seafood and food supplements

- tin in canned foods, canned beverages and canned baby foods
- 3-MCPD in vegetable protein and soy sauce (section 4)
- Dioxin and PCBs in meat, liver, fishery products, milk, eggs and oils & fats (section 5)
- Polycyclic aromatic hydrocarbons (PAH) in oils & fats, cocoa, infant foods, (smoked) meat, bivalve molluscs, fish and infant food (section 6)
- Melamine in infant food (section 7)
- Inherent plant toxins -erucic acid (section 8):
  - fats and oils and foods containing these ingredients
  - infant formula

### Official Controls of Maximum Levels in Foodstuffs

The following regulations concern the sampling methods and methods of analysis for the official controls of the levels of the different contaminants. Annex I describes the methods of sampling; Annex II concerns the sample preparation and the performance criteria for the methods of analysis:

- Nitrates: [Commission Regulation 1882/2006](#)
- Mycotoxins: [Commission Regulation 401/2006](#)
- Dioxins: [Commission Regulation 589/2014](#)
- Heavy metals, Tin, 3-MCPD and benzo(a)pyrene: [Commission Regulation 333/2007](#)

### Official Aflatoxin Controls on U.S. Products

In April 2015, the EU approved the pre-export checks (PEC) program for U.S. almonds. U.S. almonds were included in the Annex to [Commission Implementing Regulation \(EU\) 2015/949](#) which lists all EU approved Pre-export Check programs. The acceptance of the U.S. program reflects the EU's recognition of aflatoxin controls performed at U.S. origin in line with Article 23 of the EU Regulation on Official Food and Feed Controls ([Regulation \(EC\) No 882/2004](#)). The USDA Agricultural marketing Service started to issue PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which stopped being required in September 2014 when the EU voted to remove California Almonds from Special Measures.

With the publication of Commission Implementing Regulation (EU) 2015/949, all EU accepted programs have been combined in the one regulation. The U.S. peanut program which was approved in 2009 is now also covered by the general provisions of [Commission Implementing Regulation \(EU\) 2015/949](#). Under the regulation, import authorities are directed to subject consignments of U.S. almonds and peanuts with a PEC certificate to a **less than 1% control level** at the border. The PEC program is voluntary; a PEC certificate is not a requirement for import into the EU. Shipments without a PEC certificate do not benefit from the reduced inspection levels upon import in the EU.

For additional information on aflatoxin PEC certification, see:

- <http://www.almonds.com/newsletters/handle/almond-industry-flexes-its-pecs>  
<http://www.peanutsusa.org.uk/eu-food-aflatoxin-legislation>

- <http://www.ams.usda.gov/services/lab-testing/aflatoxin>

On April 1, 2015, U.S. pistachios were included in the list of products/origins subject to increased import controls under [Commission Regulation \(EC\) No 669/2009](#). Member states have to test 20 percent of all incoming shipments until the list in the Annex of the regulation is amended. This regulation does not impose any requirements on exporters.

### **Residues in Animals and Animal Product**

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/residue-plans/>

The monitoring of residues in animals and animal products is addressed separately in [Council Directive 96/23/EC](#). This directive includes the monitoring of pesticide residues as well as residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition of the use of hormones in meat production is addressed in [Council Directive 96/22/EEC](#). Directive 96/23/EC states that any third country exporting to the EU must submit a plan setting out the guarantees it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC. Furthermore, a split system has to be in place guaranteeing that animals have not been treated with growth promotants if their products will be exported to the EU.

## **Section IV. Packaging and Container Requirements**

### **A. Size & Content**

The maximum tolerable error between the actual content and the quantity indicated on the label, and methods to check this are fixed in [Council Directive 76/211/EEC](#), as amended. A small "e" of at least 3 mm on the label guarantees that the actual content corresponds to the quantity indicated. The size of the figures indicating the quantity depends on the nominal quantity:

- nominal quantity greater than 1000 g or 100 cl: at least 6 mm high
- greater than 200 g/20 cl but less than 1000 g/100 cl: at least 4 mm
- greater than 50 g/5 cl but less than 200 g/20 cl: at least 3 mm
- less than 50 g/2 cl: 2 mm. The quantity must be followed by the unit of measurement.

[Directive 2007/45/EC](#) abolished regulations on mandatory pack sizes at both EU and national levels. The Directive frees sizes for all prepackaged products except wine and spirits, and coffee. Mandatory nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC. Detailed information on "Legal Metrology" is available on the European Commission's website <http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/>.

### **B. Packaging Waste Management**

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials. [Council Directive 94/62/EC](#) harmonizes national measures concerning the management of packaging and packaging waste and its impact on the

environment. To facilitate collection, reuse and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary. A well-known and widely used recycling program is the German “green dot” system. More information can be found on the Packaging Recovery Organization Europe website which provides easy access to all Green Dot systems in Europe ([www.pro-e.org](http://www.pro-e.org)). An overview of current EU legislation applicable to packaging and packaging waste is available on the European Commission’s website <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01994L0062-20150526&qid=1446639081652&from=EN>.

## C. Materials in Contact with Foodstuffs

[European Parliament and Council Regulation 1935/2004](#) specifies the main requirements for all materials that come into contact with foodstuffs. It also sets out labeling and traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority (EFSA). Annex I to regulation 1935/2004 lists the group of materials which may be covered by specific measures. Specific measures set out additional requirements and include lists of authorized substances and materials. To date, [specific directives](#) have been developed [for plastic materials \(Commission Regulation 10/2011\)](#), [recycled plastic materials \(Commission Regulation 282/2008\)](#), [regenerated cellulose film \(Commission Directive 2007/42/EC\)](#) and [ceramics \(Council Directive 84/500/EC\)](#). In the case of ceramics, migration limits have been established for lead and cadmium. Materials must bear an indication "for food contact" or the symbol reproduced in Annex II to Regulation 1935/2004.

[Commission Implementing Regulation 321/2011](#) bans the use of Bisphenol A in plastic infant feeding bottles.

[Commission Regulation 450/2009](#) sets out definitions and authorization procedures for the use of active and intelligent materials and articles intended to come into contact with food. An [EU guidance document](#) on active and intelligent food contact materials is available on the European Commission’s website.

[Commission Regulation 2023/2006](#) lays down rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food listed in annex I to Regulation 1935/2004.

Exporters are advised to verify if a Member State follows EU provisions as Member States are allowed to authorize provisionally the use of certain substances not listed in one of the specific directives. They may also restrict or temporarily prohibit the use of certain materials authorized by the specific directives for reasons of public health. A summary of EU and national legislation as well as guidance documents and contact information with regard to the submission of applications for authorization can be downloaded from the European Commission website at [http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm).

**Check out the [European Commission’s website](#) for Information on specific substances.**

## Section V. Labeling Requirements

### A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements. On December 13, 2014, the EU's new [“Food Information to Consumers \(FIC\)” regulation 1169/2011](#) became applicable to all pre-packaged food and drink products marketed in the EU, including those imported from third countries. The mandatory nutrition declaration requirement introduced by the new FIC regulation will apply as of December 13, 2016. However, if nutrition information is provided on a voluntary basis before this date, it must comply with the new rules.

Detailed information on key changes to the EU's new food labeling requirements is available in [GAIN report “New EU Food Labeling Rules Published”](#), supplemented by [GAIN report “How to Comply with the EU's New Food Labeling Rules”](#). These reports as well as updates on EU labeling rules can be found on FAS USEU's website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/>.

In order to assist food business operators complying with the new rules, the European Commission as well as several Member State authorities and EU food federations have published guidance documents.

- European Commission: [Questions and Answers on the Application of Regulation 1169/2011 on the Provisions of Food Information to Consumers](#)
- [European Commission: Infographic on the new labeling rules](#)
- FoodDrink Europe (EU Food and Drink Industry Confederation): [Guidance on the Provision of Food Information to Consumers](#)
- U.K.: [The Food Information Regulations 2013 – Guide to compliance](#)
- Ireland: [Overview of changes to food labeling introduced under the new Food Information Regulation and New guidance for the use of food marketing terms OK](#)

### 1. Compulsory Information

Article 9 of FIC regulation 1169/2011 sets out the list of mandatory declarations on food and drink labels:

- Name of the food
- List of ingredients

- Allergens listed in Annex II
- Quantity of certain ingredients or category of ingredients
- Net quantity of the food
- Date of minimum durability of “use by date”
- Any special storage conditions and/or conditions of use
- Name of business name and address of the food business operator under whose name the food is marketed. If that operator is not established in the EU, the name and address of the importer
- Country of origin or place of provenance in accordance with the provisions of Article 26
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
- Alcoholic strength by volume for beverages containing more than 1.2% by volume of alcohol
- Nutrition declaration

## 2. Warnings on Labels

Annex III to FIC regulation 1169/2011 establishes a list of products that require a special warning on the label:

- Foods whose durability has been extended by means of packaging gases
- Foods containing sweeteners authorized under [Food Additives Regulation 1333/2008](#)
- Foods containing added sugar and sweeteners authorized under [Food Additives Regulation 1333/2008](#)
- [Foods containing aspartame authorized under Food Additives Regulation 1333/2008](#)
- [Foods containing more than 10% added polyols authorized under Food Additives Regulation 1333/2008](#)
- Confectionery and beverages containing licorice (glycyrrhizinic acid or its ammonium salt)
- Beverages containing more than 150mg/l of caffeine and foods with added caffeine
- Foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters

Annex V to [Food Additives Regulation 1333/2008](#) requires foodstuffs containing the food colors sunset yellow (E110), quinoline yellow (E104), carmoisine (E122), allura red (E129), tartrazine (E102) and



ponceau 4R (E124) to be labeled “may have an adverse effect on activity and attention in children”. Any non-edible parts of a packaging system that consumers could mistake for food must be labeled with the words “DO NOT EAT” and where technically possible carry a warning symbol.

### 3. Minimum Font Size

Article 13 of FIC regulation 1169/2011 introduces a minimum font size for printing the mandatory information on food and drink labels. As a general rule, the information must be printed in characters using of minimum font size of 1.2 mm for the “x-height” as defined in Annex IV. If the largest surface of a food package or container is less than 80 cm<sup>2</sup> the minimum font size is reduced to 0.9 mm. On packages with a printable surface smaller than 25 cm<sup>2</sup>, the nutrition declaration is not required. Packages which are smaller than 10 cm<sup>2</sup> do not need to bear a nutrition declaration nor a list of ingredients. The minimum font size does not apply to mandatory labeling requirements set out in other EU legislation such as for example the font size requirements set out in Directive 76/2011 to indicate the nominal quantity (see Section IV Packaging and Container Requirements).

**Minimum Font Size for printing mandatory information is 1.2 mm**

### 4. Language Requirements

Article 15 of FIC regulation 1169/2011 stipulates that the mandatory information should be provided in “a language easily understood by the consumers of the Member States where the food is marketed”. In practice, this means the official language(s) of that Member State. Member States may specify which information needs to be provided in one or more official EU languages. In order to avoid non-compliance with the new labeling rules, translations of mandatory information must be accurate. Automated online translation tools may generate incorrect translations and should not be used unless edited. Please consult the [Member State FAIRS reports](#) for information on specific Member State language requirements.

**U.S. Exporters should verify with their importers about additional Member State language requirements**

### 5. Ingredients List

The list of ingredients must be preceded by the word “ingredients”. All ingredients must be designated by their specific name and listed in descending order of weight. Ingredients present in the form of engineered nanomaterials must be indicated in the list of ingredients followed by the word “nano” in brackets. Annex VII to FIC regulation 1169/2011 sets out specific provisions concerning the indication of ingredients and categories of ingredients in the list of ingredients. This Annex requires the mandatory



indication of the source of vegetable oils and fats.

**In the list of ingredients “Vegetable oils” and “vegetable fats” must be followed by a list of the specific vegetable sources**

## 6. Allergen Labeling

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/allergen-labeling/>

FIC regulation 1169/2011 introduced important changes for allergen labeling. Article 21 of the FIC regulation stipulates that each product or substance capable of inducing an allergic reaction must be indicated in the list of ingredients with reference to the name of the substance or product as listed in Annex II to the FIC regulation. The name of the substance or product must be highlighted through a typeset that clearly distinguishes it from the other ingredients, for example in bold or with a background color.

Example: “tofu” (soya) – “whey” (milk)

Where an ingredients list is provided, the voluntary use of warning boxes or statements such as “contains X” to repeat the presence of the allergenic ingredients is no longer allowed.

On products that do not require an ingredients list, such as for example wine, the presence of allergens must be indicated using the word “contains” followed by the name of the substance or product as listed in Annex II to the FIC regulation. Allergen labeling is mandatory on all alcoholic beverages and must respect the minimum font size requirement. Member States may decide in which language(s) allergens should be indicated on the label.

In November 2014, the European Commission launched a public consultation on a [Guidance Document on Allergen Labeling](#). The consultation closed on January 4, 2015. For more information please consult DG SANTE’s website: [http://ec.europa.eu/dgs/health\\_food-safety/dgs\\_consultations/food/consult\\_20150104\\_allergy-intolerance\\_en.htm](http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consult_20150104_allergy-intolerance_en.htm).

Other guidance documents:

- [Allergen Labeling – Annex 3 \(FoodDrinkEurope\)](#)
- [Advice on Food Allergen Labeling \(U.K. Food Standards Agency\)](#)
- [Allergy: what to consider when labeling food \(U.K. Food Standards Agency\)](#)
- [Food allergen labeling – technical guidance \(U.K. Food Standards Agency\)](#)

**Allergens must be highlighted in the list of ingredients**

## 7. Minimum Durability

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/shelf-life/>

Annex X to FIC regulation 1169/2011 sets out rules for the indication of the date of minimum durability, use-by date and date of freezing. The use-by date must be indicated on individual pre-packed portions. The durability date **AND** the date of (first) freezing preceded by the words “frozen on” is required on labels of frozen meat, frozen meat preparations and frozen unprocessed fishery products.

**Dates must be given in the following order: day/month/(if required) year**

## 8. Quantitative Ingredients Declaration (QUID)

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/quantitative-ingredients-declaration/>

Article 22 of the FIC regulation requires the indication of the quantity of an ingredient or category of ingredients in the following cases:

- Where the ingredient or category of ingredients appears in the name of the food or is usually associated with that name by the consumer
- Where the ingredient or category of ingredients is emphasized on the labeling in words, pictures or graphics
- Where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from similar products

The QUID declaration, expressed as a percentage, must appear either in or immediately next to the name of the food or in the list of ingredients. Annex VIII to the FIC regulation sets out the technical rules and exemptions from the QUID requirement.

European Commission guidelines on QUID can be downloaded from their website at [http://ec.europa.eu/food/safety/docs/labelling\\_legislation\\_guidance\\_quid\\_en.pdf](http://ec.europa.eu/food/safety/docs/labelling_legislation_guidance_quid_en.pdf).

**If an ingredient is emphasized on the label, the quantity (%) must be indicated in the list of ingredients**

**Example: “made with butter” – QUID for butter**

## 9. Additives & Flavorings

Annex VII, Part C to FIC regulation 1169/2011 lists the categories of additives which must be designated by the name of their category, followed by their specific name or E-number. Part D of the same Annex sets out rules for the indication of flavorings, smoke flavorings and the use of the term “natural”.

## 10. Country of Origin Labeling (COOL)

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/country-of-origin-labeling/>

Before the adoption of FIC regulation 1169/2011 COOL was already mandatory for honey, fruit and vegetables, olive oil, fishery and aquaculture products and beef. The FIC regulation extends the mandatory COOL requirement to fresh, chilled and frozen pork, sheep and goat meat and poultry. Under Article 26 of the FIC regulation, mandatory COOL applies in the following cases:

- Where failure to indicate the country of origin or place of provenance might mislead the consumer
- For fresh, chilled and frozen pork, sheep and goat meat and poultry (see “Meat Labeling”)
- When the country of origin is given voluntarily, i.e. on products for which COOL is not mandatory, but the origin of the primary ingredient is not the same as that of the food product. In such case, the label must indicate that the country of origin of the primary ingredient is different from that of the food product.

Detailed information on COOL is provided [in GAIN report “The EU’s Country of Origin Labeling Policy”](#). For more information on the status of required Commission reports see DG SANTE’s website [http://ec.europa.eu/food/safety/labelling\\_nutrition/labelling\\_legislation/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/index_en.htm).

**Regulation 1169/2011 extends mandatory COOL to fresh, chilled and frozen pork, sheep and goat meat and poultry**

## 11. Alcoholic Beverages

Alcoholic beverages containing more than 1.2% of alcohol by volume are still exempted from the obligation to bear a nutrition declaration and a list of ingredients. The European Commission is preparing a report examining whether the exemption for alcoholic beverages should be maintained or not. Allergen labeling is compulsory on all alcoholic beverages (see “Allergen Labeling”). On beverages containing more than 1.2% of alcohol by volume (excluding wines), the actual alcoholic strength by volume must be indicated in accordance with Annex XII to FIC regulation 1169/2011. The alcoholic strength must be indicated by a figure with maximum one decimal place followed by the symbol “%

vol.”. The alcoholic strength must be given in the same field of vision as the product name and the net quantity. For wines, rules for the indication of the alcoholic strength are set out in specific legislation.

**The alcoholic strength must be given in the same field of vision as the product name and the net quantity**

## 12. Nutrition Declaration

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/nutritional-labeling/>

Under FIC regulation 1169/2011, the nutrition declaration will become mandatory on December 13, 2016. However, food business operators who provide nutrition information on a voluntary basis between December 13, 2014 and December 13, 2016, must comply with the rules set out in Articles 29-35 of the FIC regulation. Annex V to the FIC regulation lists foodstuffs which are exempted from the mandatory nutrition declaration requirement. The nutrition declaration must be presented, if space permits, in tabular format with the numbers aligned and where space does not permit, in linear format. All elements of the mandatory nutrition declaration should be in the same field of vision on the food label or package. Mandatory content of the nutrition declaration:

- Energy value: expressed in kilojoules (kj) and kilocalories (kcal)
- **In this particular order:** amounts of fat, saturates, carbohydrate, sugars, protein and salt, expressed in grams (g), milligrams (mg) or micrograms (µg) per 100 grams or per 100 milliliters

Nutrition declarations per portion or per consumption unit, in addition to the declaration per 100 grams or milliliters are allowed provided that the number of portions/consumption units is clearly indicated on the package. The salt content must be expressed as “salt” not “sodium” but where appropriate, a statement indicating that the salt content is exclusively due to the presence of naturally occurring sodium may appear in close proximity to the nutrition declaration.

The following elements may, on a voluntary basis, be repeated on the front label:

- Energy value
- Energy value together with the amounts of fat, saturates, sugars and salt

The content of the mandatory nutrition declaration may be supplemented with the indication of the amounts of one or more of the following:

- Monounsaturates
- Polyunsaturates

- Polyols
- Starch
- Fiber
- Vitamins and minerals listed in Part A of Annex III to the FIC regulation (incl. percentage of reference intakes)

Detailed rules on the presentation of the nutrition declaration are set out in Annex XV to the FIC regulation.

Annex V to the FIC regulation establishes a list of products that are exempted from the mandatory nutrition declaration requirement.

The EU's Food & Drink Industry Federation "FoodDrinkEurope" has launched a website explaining "reference intakes" to food business operators and consumers: <http://referenceintakes.eu/reference-templates.html>. For detailed information on the nutrition panel see the guidance documents listed in "General Requirements" (Chapter A).

**Nutrition information must be presented in tabular format and in a specific order expressed per 100 grams/milliliters**

### 13. Use of Stickers

Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC regulation 1169/2011. On this issue, the European Commission refers to point 2.1.1 of [their Questions and Answers on the Application of Regulation 1169/2011](#) document which says that "labels should not be easily removable so as to jeopardize the availability or the accessibility of the mandatory food information to the consumer". Some Member States may allow the use of stickers while other may not. Please consult the [Member State FAIRS reports](#) for more information.

**U.S. Exporters should check with their importers whether the destination Member State allows the use of stickers**

### 14. Samples

FIC Regulation 1169/2011 does not include any provisions on samples.

## 15. Transitional Measures

Transitional measures for compliance with the new rules are set out in Article 54 of the FIC regulation. Foods placed on the market or labeled prior to December 13, 2014, which comply with the old requirements but not with the new, may be marketed until stocks are exhausted. Exporters must provide documentation demonstrating that products were labeled before December 13, 2014. Although the new nutrition labeling requirements only become mandatory on December 13, 2016, nutrition information provided on a voluntary basis must comply with the new rules as of December 13, 2014.

## 16. Checklist for Compliance with new FIC Rules

<b>FOOD LABELS</b>	
Language / Specific Member State requirements	
Minimum font size	
Name of food (must include specific treatments such as “refrozen”, “smoked”, “powdered”, percentage of added water to meat and fishery products	
Warnings (Annex III to FIC regulation lists products that require a warning label)	
Instructions for use (symbols are allowed IN ADDITION to text)	

<b>ALLERGEN LABELING</b>	
Allergens listed in Annex II to FIC regulation must be indicated	
Allergen boxes are no longer allowed when an ingredients list is provided	
Each allergen must be highlighted (bold, background color) in the list of ingredients	
“Contains + name of allergen” where no ingredients list is provided	

<b>INGREDIENTS LIST</b>	
Heading must include the word “Ingredients” (do not highlight)	
All ingredient must be listed in descending order of weight	
“Nano” in brackets to indicate presence of engineered nanomaterials	
Quantitative Ingredients Declaration (QUID) for ingredients given special emphasis	
Source of vegetable oil or fat must be indicated	
Proteins added to meat products must be indicated	

<b>DATE OF MINIMUM DURABILITY</b>	
Instructions listed in Annex X to FIC regulation	
“Use by” date on highly perishable foods / on each individual pre-packed portion / storage instructions	
“Best before” / “Best before end” on other foods	
Durability AND “frozen on” date on frozen products	
Reference to where the date is given on the label	

<b>ALCOHOLIC STRENGTH</b>	
Instructions listed in Annex XII to FIC regulation	
Actual alcoholic strength by volume of alcohol of beverages containing more than 1.2% by volume of alcohol must be indicated as “alcohol” or the abbreviation “alc.” X% vol.	
Product name, net quantity and alcohol strength must be indicated in the same field of vision	

<b>COUNTRY OF ORIGIN (COOL)</b>	
Mandatory COOL where failure to indicate this would mislead consumer	
Mandatory COOL for meat from sheep, goats, poultry and pigs	
Mandatory COOL for other products may be adopted in near future	

<b>Mandatory Nutrition Declaration (applicable as of December 13, 2016 – nutrition panels provided before this date must comply with FIC regulation)</b>	
Instructions listed in Annex XV to FIC regulation	
Tabular format (linear format where space does not permit tabular format)	
Expressed per 100g/ml	
Energy in KJ and kcal	
In this particular order, amounts of:	
Fat	
Saturates	
Carbohydrate	
Sugars	
Protein	
Salt (not sodium)	

<b>Voluntary Nutrition Declaration (may complement Mandatory Nutrition Declaration)</b>	
Mono saturates	
Polyunsaturates	
Polyols	
Starch	
Fibre	
Vitamins and minerals listed in Annex XIII to FIC regulation	
Energy value or Energy Value together with Fats, Saturates, Sugars, Salt may be repeated	
Reference Intake (RI) set out in Annex XIII per portion or consumption unit (must include energy value per 100g/ml and per portion)	

See also Commission memo [“Main innovations introduced by Regulation 1169/2011”](#) and [infographic “New EU food labeling rules”](#).

## B. Other Specific Labeling Requirements

The EU's "Food Information to Consumers" regulation 1169/2011 sets out horizontal rules applicable to all products. Sectoral or "vertical" legislation exists for a number of products. Labeling requirements set out in product-specific legislation complement the horizontal rules set out in regulation 1169/2011. For example, EU wine regulations do not include provisions on allergen labeling. This means that wine labels not only have to comply with the requirements set out in wine regulation 607/2009 but also with the allergen labeling requirement set out in FIC regulation 1169/2011.

**U.S. Exporters should be aware that different pieces of legislation may apply to single products**

### 1. Nutrition Claims

The Annex to [Nutrition & Health Claims Regulation 1924/2006](#) lists the EU authorized nutrition claims and their conditions of use. The use of nutrition claims not included in the annex is not allowed.

### 2. Health Claims

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/nutrition-health-claims/>

Rules on the use of health claims are set out in [Nutrition & Health Claims Regulation 1924/2006](#). [Regulation 432/2012](#) establishes the EU positive list of functional health claims and their conditions of use. Any producer can use the permitted health claims provided the conditions set out in Regulation 432/2012 are met. The EU's [online "Register of Nutrition and Health Claims"](#) lists the authorized health claims as well as the rejected claims and the reasons for their non-authorization. Since December 14, 2012, all claims that are not authorized and not on hold or under consideration are prohibited. Food products carrying claims must also comply with the provisions of the EU's "[Food Information to Consumers \(FIC\)](#)" regulation 1169/2011. [Commission Implementing Decision 2013/63](#) sets out guidelines for national control authorities as regards the implementation of specific conditions for permitted health claims.

The authorization of health claims referring to botanical substances was put on hold because of the potential conflict with the Traditional Herbal Medicinal Products Directive. In October 2015, the European commission published a "[roadmap](#)" to evaluate Regulation 1924/2006. The evaluation will focus on two specific elements: the authorization of health claims referring to botanical ingredients and the establishment of nutrient profiles. Regulation 1924/2006 required the Commission to establish nutrient profiles, thresholds for salt, fat and sugar above which nutrition and health claims would be restricted. To date, nutrient profiles have not yet been adopted and the Commission will now assess whether they are necessary to ensure adequate implementation of the regulation. The evaluation should be completed by June 2017 and will be used to decide whether the nutrition and health claims regulation



should be amended.

The list of permitted functional health claims is different from the individual applications for health claims relating to disease risk reduction and claims referring to the health and development of children which require an authorization on a case-by-case basis, following the submission of a scientific dossier to EFSA. A simplified authorization procedure has been established for health claims based on new scientific data.

[Regulation 353/2008](#) sets out implementing rules for applications for the authorization of health claims as provided for in Article 15 of Regulation 1924/2006. [GAIN Report E48055](#) describes how application dossiers for authorization of health claims should be prepared and presented. A guidance document on how companies can apply for health claim authorizations can be downloaded from EFSA's website at <http://www.efsa.europa.eu/en/nda/ndaclaims.htm>.

[Commission Regulation 907/2013](#) establishes rules for the use of “generic descriptors” which could be interpreted by consumers as health claims. Generic descriptors such as “digestive biscuits” and “cough drop” would normally be banned under Regulation 1924/2006 because they suggest a beneficial effect on health but the implied health benefit has not been evaluated scientifically by the European Food Safety Authority (EFSA). For more information see [GAIN report “Health Claims – New EU Regulation on Generic Descriptors”](#).

Trademarks and brand names that suggest health and/or nutritional benefits but do not comply with the new rules must be entirely removed from the EU market by January 19, 2022.

**Health Claims are only allowed if the importance of a balanced diet and healthy lifestyle is also stated on the label**

### 3. Genetically Modified Foods Labeling

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/labeling-of-genetically-modified-products/>

Labeling regulations for genetically modified (GM) food products are established by [Regulation 1829/2003](#) (articles 12-13). These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling. The traceability rules require all business operators to transmit and retain information on GM products in order to identify both the supplier and the buyer of the GM product.

Each individual genetically modified organism (GMO) must be approved before it can be used in food and feed. The EU register of authorized GMOs can be consulted on the European Commission's website at [http://ec.europa.eu/food/plant/gmo/eu\\_register/index\\_en.htm](http://ec.europa.eu/food/plant/gmo/eu_register/index_en.htm). All food products containing or consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs must be

labeled even if they no longer contain detectable traces of GMOs. The labeling requirement does not apply to foods containing GMOs in a proportion equal to or less than 0.9 percent of the food ingredients considered individually, provided their presence is adventitious or technically unavoidable. Above this level, all products must be labeled using the following wording:

- Where the food consists of more than one ingredient, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GM component should be labeled “contains [name of ingredient] produced from genetically modified [name of organism]”.

*Example: a biscuit containing soy flour derived from GM-soy must be labeled “contains soy flour from genetically modified soy”.*

- Where the ingredient is designated by the name of a category (e.g. vegetable oil), the words “contains genetically modified [name of organism]” or “contains [name of ingredient] produced from genetically modified [name of organism]” must be used.

*Example: for vegetable oils containing rapeseed oil produced from genetically modified rapeseed, the reference “contains rapeseed oil from genetically modified rapeseed” must appear in the list of ingredients.*

The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.

- Where there is no list of ingredients, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must appear clearly in the labeling.

*Example 1: “a spirit containing caramel produced from genetically modified corn”.*

*Example 2: “genetically modified sweet corn”.*

More information can be found on the European Commission’s website:

[http://ec.europa.eu/food/plant/gmo/traceability\\_labelling/index\\_en.htm](http://ec.europa.eu/food/plant/gmo/traceability_labelling/index_en.htm) and in the [annual GAIN report on Agricultural Biotechnology](#) (published July 2015).

**Non-GMO:** EU-harmonized legislation defining “non-GM”, ‘GM-free’ or similar labeling terms does not (yet) exist. National provisions and operator-specific “GM-free” and similar labeling schemes have been developed in several Member States.

**A Commission proposal presented in April 2015 allowing Member States to restrict the use or ban genetically modified food and feed is currently under discussion.**

#### 4. Organic Food Labeling

[Council Regulation 834/2007](#) is the EU's general framework regulation that sets out rules for organic production and labeling. [Commission Regulation 889/2008](#) sets out detailed rules for the implementation of Regulation 834/2007.

The term “organic” and all its derivatives or diminutives such as “bio” and “eco” may be used only to label products that comply with EU organic production rules and if at least 95% of the ingredients of agricultural origin are organic. For products containing less than 95% organic ingredients, the term “organic” may be used only to indicate individual organic ingredients in the list of ingredients. When reference is made to the organic production method in the ingredients list, the total percentage of organic ingredients must be indicated. The Annex to Regulation 834/2007 lists the term “organic” in all the official EU languages.

For more information see the European Commission's website at [http://ec.europa.eu/agriculture/organic/eu-policy/legislation\\_en#regulation](http://ec.europa.eu/agriculture/organic/eu-policy/legislation_en#regulation).

On July 1, 2012, the use of the EU organic logo became mandatory on all pre-packaged organic products produced in the EU. Organic products imported from third countries may carry the EU organic logo if they comply with the EU production rules. When the EU organic logo appears on the label, the indication of the place of farming is required.

**US-EU Equivalency Arrangement:** The US-EU Organic Equivalence Arrangement took effect on June 1, 2012. The U.S. and EU have recognized each other's organic production rules and control systems as equivalent under their respective rules. Organic products certified to the USDA organic standards may be sold and labeled as organic in the EU. Both the USDA organic seal and the EU organic logo may be used on products traded under this Arrangement. When using the EU organic logo, exporters must meet all the EU labeling requirements.

For more information please see [USDA Agricultural Marketing Service: National Organic Program \(International Trade Policies: European Union\)](#)

**Organic Wine:** [Commission Implementing Regulation 203/2012](#), applicable since August 1, 2012, sets out the conditions to label wine as organic. It allows the use of the term “organic wine” but NOT the term “wine made from organic grapes”. Sorbic acid and desulfuration are not allowed and the level of sulfites must be at least 30-50 mg per liter lower than their conventional equivalent. As Regulation 203/2012 was only published in March 2012, a month after the U.S. and the EU signed the Equivalency Arrangement, organic wine was not included in the deal. [Commission Implementing Regulation 508/2012](#), published in June 2012, includes U.S. organic wines in Annex III to [Regulation 1235/2008](#) on import arrangements with third countries. Only U.S. organic wines certified to comply with the EU's organic wine making rules can be imported into the EU.

**A Commission proposal to revise the current rules on organic food production and labeling is expected to be adopted in 2016. The new regulation would not affect the U.S-EU Equivalency Arrangement.**

## **5. Wine, Beer and Other Alcoholic Beverages**

**Wine:** The EU's [Single Common Market Organization Regulation 1308/2013](#) establishes framework rules for wine. [Commission Regulation 607/2009](#), as amended by [Commission Implementing 1185/2012](#), lays down detailed rules on protected designations of origin and geographical indications, traditional terms and labeling. For detailed information on the EU's wine legislation see the European Commission's website [http://ec.europa.eu/agriculture/wine/legislation/index\\_en.htm](http://ec.europa.eu/agriculture/wine/legislation/index_en.htm).

Chapter II of Regulation 607/2009 establishes the application procedure for a designation of origin or a geographical indication. Designation of origin or geographical indications which have been accepted are entered in a "Register of protected designations of origin and protected geographical indications" maintained by the European Commission. The register lists geographical indications protected in the EU as well as third countries' geographical indications and names of origin protected under bilateral wine trade agreements. The register is available through the [Commission's online "E-Bacchus" database](#).

Chapter III of Regulation 607/2009 sets out rules on the use of traditional terms. The ["E-Bacchus" database](#) lists the traditional terms that are protected in the EU. The use of expressions such as "style", "type", "method", "as produced in", "imitation", "flavor", "like" or similar, accompanied by a traditional term included in the E-Bacchus database is not allowed. Third countries may use traditional terms not listed in the database. Since Regulation 607/2009 became applicable, the European Commission received several applications from third countries – most of which came from the United States - to use EU protected traditional terms. [Commission Implementing Regulation 723/2012](#) allows the use of the traditional term "Cream" on U.S. grapevine products. Five years after receiving the applications, the European Commission has not made any progress on allowing the use of other traditional terms such as "Chateau" on U.S. grapevine products.

Chapter IV of Regulation 607/2009 sets out rules for the indication of compulsory and optional information on wine labels. The mandatory information must appear in the same field of vision on the container, in such a way that all the information (except the lot number) is readable without having to turn the container. The mandatory information must be clearly distinguishable from surrounding text or graphics.

The indication of the wine grape variety on the label is optional. For third country wines, the wine grape variety must be included in at least one of the lists established by the "international Organization of Vine and Wine (OIV), the "Union for the Protection of Plant Varieties (UPOV)" or the "International Board for Plant Genetic Resources (IBPGR)". Terms such as "barrel matured", "barrel aged" (listed in Annex XVI to Regulation 607/2009) may not be used on wines produced with the aid of oak chips. The use of the term "alcohol free wine" is not allowed in several Member States.

Examples on compliant wine labels can be found in the [U.K. Food Standards Agency's "Wine Labeling Guidance"](#).

**Allergen Labeling:** The indication of allergens listed in Annex II to ["Food Information to Consumers \(FIC\)" regulation 1169/2011](#) is mandatory on all food and beverage labels. [Commission Implementing Regulation 579/2012](#) sets out the modalities for the labeling of allergens on wine. A wine label must state that it "contains" one or more of the following allergens: "sulphites", "sulfites", "sulphur dioxide", "sulfur dioxide", "egg", "egg protein", "egg product", "egg lysozyme", "egg albumin", "milk", "milk product", "milk casein" or "milk protein". The translation of these terms in all the official EU languages is available in Part A of the Annex to Regulation 579/2012. Information on the authorized languages to label allergens in the different EU Member States is available on the European Commission's website at <http://ec.europa.eu/agriculture/markets/wine/sulphites.pdf>. The terms designating the allergenic ingredient may be supplemented by the pictograms laid down in Part B of the Annex to Regulation 579/2012. Allergen labeling must respect the minimum font size requirement (1.2 mm) established by FIC regulation 1169/2011. Member States may decide in which language(s) allergens should be indicated on the label.

**US-EU Wine Agreement:** In March 2006, the U.S. and the EU and the U.S. signed the ["Agreement between the United States and the European Community on Trade in Wine"](#). The Agreement covers wine with an actual alcohol content of not less than 7% and not more than 22%. All U.S. wine imports must be accompanied by certification and analysis documentation using the format specified in Annex III (a) to the Agreement. More information on the simplified EU import certificate form can be obtained from the Alcohol and Tobacco Tax and Trade Bureau at [http://www.ttb.gov/agreements/us\\_ec\\_wine\\_agreement.shtml](http://www.ttb.gov/agreements/us_ec_wine_agreement.shtml) and in their guidance document "Procedures for exporting wine to the EU". The Agreement's "Protocol on Wine Labeling" sets conditions for the use of optional particulars on wine labels. [Commission Regulation 1416/2006](#) concerns the protection of U.S. names of origin in the EU. Information on the US-EU Wine Agreement can also be obtained from the U.S. Dept. of the Treasury - Alcohol and Tobacco Tax and Trade Bureau at <http://www.ttb.gov/importers/importing-exporting.shtml>.

**Spirit Drinks:** [European Parliament and Council Regulation 110/2008](#) lays down general rules on the definition, description and presentation of spirit drinks. [Commission Implementing Regulation 716/2013](#) lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and geographical indications of the spirit drinks. This regulation prohibits the use of the term "spirit drink" as part of a compound term. [Commission Regulation 936/2009](#) applies the agreements between the EU and third countries on the mutual recognition of certain spirit drinks. Under this regulation, "Tennessee Whisky" and "Bourbon Whisky" are protected product designations.

**Nominal Quantity:** Mandatory nominal quantities for wines and spirits are set out in the Annex to [Directive 2007/45/EC](#).

**Beer:** There is no specific EU-harmonized legislation for beer, although some member states have adopted national provisions to make the list of ingredients compulsory. All alcoholic beverages must comply with the allergen labeling requirements (see "Wine").

## Alcoholic beverages must comply with the EU's allergen labeling rules set out in FIC Regulation 1169/2011

### 6. Special Use Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/dietetic-foods/>

On July 20, 2016, the EU's new rules on dietetic foods set out in European Parliament and Council Regulation 609/2013 will become applicable and repeal the existing rules on "foodstuffs intended for particular nutritional uses". The scope of this regulation is limited to infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Under the new rules, pictures of infants are no longer allowed on the packaging and no pictures or text may idealize the use of such formula. Foods that no longer fall within the scope of Regulation 609/2013, such as for example low calorie cereal bars and slimming products, will be regarded as "normal foods" and must comply with the [Food Information to Consumers Regulation 1169/2011](#) and [Nutrition and Health Claims Regulation 1924/2006](#). For more information see [GAIN report "New EU Rules on Dietetic Foods"](#) and the European Commission's website at [http://ec.europa.eu/food/safety/labelling\\_nutrition/special\\_groups\\_food/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/index_en.htm).

Until Regulation 609/2013 becomes applicable, the current rules set out in framework [Directive 2009/39/EC](#) still apply. Foodstuffs for particular nutritional uses are defined as foodstuffs, which due to their special composition or manufacturing process can clearly be distinguished from foodstuffs for normal consumption. [Commission Regulation 953/2009](#) lists the substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses.

Provisions regarding compositional and hygiene requirements, quality of raw materials, a list of additives/substances, specific labeling requirements, sampling procedures and analysis methods have been laid down in specific directives for four product categories:

- [Commission Directive 2006/125/EC](#) on processed cereal-based foods and baby foods for infants and young children.
- [Commission Directive 96/8/EC](#) on foods intended for use in energy-restricted diets for weight reduction.
- [Commission Directive 2006/141/EC](#) on infant formula and follow-on formula, amended by [Commission Regulation 1243/2008](#) as regards compositional requirements for certain infant formulae.
- [Commission Directive 1999/21/EC](#) on dietary foods for special medical purposes.

[Commission Regulation 41/2009](#) lays down new EU harmonized rules for the composition and labeling



of foodstuffs suitable for people who are intolerant to gluten. This regulation sets conditions for the use of the terms “very low gluten” and “gluten-free”. [Commission Regulation 1155/2013](#), applicable as of July 20, 2016, transfers the provisions relating to “gluten-free” and “lower gluten” food to [Food Information to Consumers Regulation 1169/2011](#). [For more information see GAIN report “New EU Rules on Dietetic Foods”](#).

Specific directives on foods and beverages for athletes or on foods intended for diabetics are still subject to Member State legislation. The marketing of dietetic foods for which no specific rules have been established must be notified to the Member State where the food is sold. A list of competent Member State authorities can be downloaded at [http://ec.europa.eu/food/food/labellingnutrition/nutritional/list\\_auth\\_art11\\_en.pdf](http://ec.europa.eu/food/food/labellingnutrition/nutritional/list_auth_art11_en.pdf).

**Starting July 20, 2016, new dietetic food rules will apply**

## **7. Meat Labeling**

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/beef-labeling/>

### **Beef**

[Regulation 1760/2000](#) sets out rules for compulsory and voluntary beef labeling. Detailed rules for the implementation of Regulation 1760/2000 are set out in [Regulation 1825/2000](#). Under the compulsory beef labeling scheme, labels for all bovine meat must indicate the following information:

- “Born in: name of third country”
- “Reared in: name of third country or third countries”
- For beef derived from animals born, raised and slaughtered in the same third country, the above indications may be combined as “Origin: name of third country”
- A reference number ensuring the link between the meat and the animal or animals
- “Slaughtered in: third country / approval number of slaughterhouse”
- “Cutting in: third country / approval number of cutting plant”
- A traceability code linking the meat to the animal or a group of animals representing the production of maximum one day

[Regulation 653/2014](#), an amendment to Regulation 1760/2000, changed the rules for voluntary labeling. Voluntary beef labeling has to comply with the rules set out in the [“Food Information to Consumers” Regulation 1169/2011](#). Definitions and requirements applicable to terms and or categories of terms that may be put on labels of pre-packed fresh and frozen beef and veal will be adopted at a later date.

## Veal

Annex VII to [European Parliament and Council Regulation 1308/2013](#) classifies bovine animals aged less than 12 months in two categories: 1) “category V” - bovine animals aged 8 months or less and 2) “category Z” - bovine animals aged more than 8 months but less than 12 months. For both categories, Annex VII lists the sales descriptions in the different Member States languages and the mandatory labeling requirements.

## Pork, Sheep, Goats and Poultry

[Commission Implementing Regulation 1337/2013](#) sets out new rules for the indication of the country or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry. The following new labeling requirements will apply as of April 1, 2015:

1) The indication **“Reared in: name of the Member State of third country”** in accordance with the following criteria:

For **swine**:

- In case the animal is slaughtered older than 6 months, the Member State or third country in which the last rearing period of at least 4 months took place
- In case the animal is slaughtered younger than 6 months and with a live weight of at least 80 kg, the Member State or third country in which the rearing period after the animal has reached 30 kg took place
- In case the animal is slaughtered younger than 6 months and with a live weight less than 80 kg, the Member State or third country in which the whole rearing took place

For **sheep and goats**:

- The Member State or third country in which the last rearing period of at least 6 months took place, or in cases the animal is slaughtered younger than 6 months, the Member State or third country in which the whole rearing period took place

For **poultry**:

- The Member State or third country in which the last rearing period of at least one month took place or, in case the animal is slaughtered younger than one month, the Member State or third country in which the whole rearing period after the animal was placed for fattening took place

In cases where any of the above rearing periods are not attained in any of the Member States or third countries, the place of rearing must be indicated as “Reared in: several Member States of the EU” or “Reared in: several non-EU countries” or “Reared in several EU and non-EU countries”. As an alternative the place of rearing may also be indicated as “Reared in: list of the Member States or third countries where the animal was reared”.

The indication “Origin: name of Member State or third country” may be used in cases where the meat



has been obtained from animals born, reared AND slaughtered in one single Member State or third country.

2) The indication **“Slaughtered in: name of the Member State or third country”**. By way of derogation for meat imported from third countries, in cases where information on the rearing periods is not available, the meat must be labeled as “Reared in: non-EU” and “Slaughtered in: name of the third country where the animal was slaughtered”.

## 8. Health and Identification Marks

The EU’s “Food Hygiene Package” introduced new rules concerning the application of health and identification marks. Chapter III of [European Parliament and Council Regulation 854/2004](#) lays down rules for applying a health mark to fresh meat. More information on the EU health mark is available on USDA’s Food Safety Inspection Service’s website at <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/European-Union>. Annex II to [European Parliament and Council Regulation 853/2004](#) lays down rules for applying an identification mark to products of animal origin. Linear presentation of the required information is allowed only for imports from EU-approved establishment in third countries.

## 9. Frozen Foodstuffs

[Council Directive 89/108/EEC](#) sets rules for quick-frozen foodstuffs and for their packaging and labeling. Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication “quick-frozen”, the date of minimum shelf life, the period during which the purchaser may store the product, the storage temperature and/or type of storage equipment required, batch identification and a clear indication of the type “do not re-freeze after defrosting”. Annex VI, Part A, [to FIC regulation 1169/2011](#) stipulates that foods that have been frozen before sale and which are sold defrosted, the name of the food must be accompanied by the designation “defrosted”.

For food of animal origin, [Commission Regulation 16/2012](#) amending [Food Hygiene Regulation 853/2004](#), requires food business operators to provide the date of production AND the date of freezing to the buyers and upon request, to the competent authorities. Where a food is made from a batch of raw materials with different dates of production and freezing, the older dates of production and/or freezing must be made available.

Annex III to FIC regulation 1169/2011 requires that labels on frozen meat, frozen meat preparations and frozen unprocessed fishery products indicate the date of freezing or the date of first freezing in cases where the product has been frozen more than once.

**Date of first freezing must be indicated when a product has been frozen more than once**

## 10. Vertical & Product-Specific Legislation

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/>

Vertical legislation on the manufacture and marketing of specific products has been developed for [sugars](#), [cocoa and chocolate products](#), [honey](#), [fruit juices and similar products](#), [preserved milk](#), [coffee extracts and chicory extracts](#) and [fruit jams and similar products](#).

**Fruit Juices:** [Directive 2012/12/EU](#), published in April 2012, set out new labeling rules for fruit juices and fruit nectars. This directive amended [framework Directive 2001/112/EC](#) relating to fruit juices and certain similar products intended for human consumption. Products placed on the market or labeled before October 28, 2013, could continue to be marketed until April 28, 2015. Detailed information on key changes introduced by the new directive can be found in [GAIN report “New EU Fruit Juice Labeling Rules.”](#)

**Honey:** On May 15, 2014, the EU adopted [Directive 2014/63/EU](#) amending [Directive 2001/110/EC](#) relating to honey. It defines pollen as a natural constituent of honey and should not be considered to be an ingredient of honey. This means that GM pollen present as a quantity of more than 0.9% of the honey (not the pollen) would need to be labeled as such. Since pollen only forms around 0.5% of any batch of honey, it will never exceed the GM labeling threshold.

**Single Common Market Organization:** [European Parliament and Council Regulation 1308/2013](#) establishes a single common market organization (CMO) for all agricultural products. The single CMO provides definitions and marketing rules for rice, sugar, beef and veal, milk and milk products, eggs and poultry meat, olive oil, fruit and vegetables, spreadable fats and wine.

## Section VI. Other Specific Standards

### A. Novel Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/novel-foods/>

#### Current Rules

The [Novel Food Regulation 258/97](#) lays down detailed rules for the authorization of novel foods and novel food ingredients. It defines novel foods as foods and food ingredients that were not used to a significant degree in the Novel food categories consist of food and food ingredients:

- with a new intentionally modified primary molecular structure, or
- consisting of, or isolated from, micro-organisms, fungi or algae, or
- consisting of, or isolated from plants or animals, except for foods and food ingredients obtained by traditional propagating or breeding practices with a history of safe use, or

- to which a production process not currently used has been applied, where that process changes the composition or structure of the food or food ingredient significantly

An Information and Guidance Document on “human consumption to a significant degree” is published on the European Commission’s website: [http://ec.europa.eu/food/safety/docs/novel-food\\_guidance\\_human-consumption\\_en.pdf](http://ec.europa.eu/food/safety/docs/novel-food_guidance_human-consumption_en.pdf).

Unlike food additives and vitamins and minerals, a positive list of novel foods and ingredients does not yet exist. A Novel Foods Catalog is available on the website of the European Commission but has no legal value. U.S. exporters are advised to check the legal status of novel food ingredients before exporting to the EU. For more information see the European Commission’s website at [http://ec.europa.eu/food/safety/novel\\_food/index\\_en.htm](http://ec.europa.eu/food/safety/novel_food/index_en.htm) and [GAIN report “Negative List for Novel Foods and Ingredients”](#).

### **New Rules as of 2017**

A new [EU framework regulation 2015/2283 on Novel Foods](#) was adopted in November 2015 and published in Official Journal L 327 on December 11, 2015. Most provisions of the new Novel Foods Regulation will become applicable on January 1, 2018. Main elements of the new Novel Foods Regulation include:

**Definition:** A novel food is defined as food that has been not consumed to a significant degree in the EU before May 15, 1997 AND falling within at least one of the categories listed in Article 3 of the new regulation. The definition also covers food produced with “non-traditional breeding techniques”.

**Authorization procedure:** Under the new centralized authorization procedure authorizations would take up to 18 months compared to 42 months under the current rules. Applications for authorizations must be submitted to the European Commission and the European Food Safety Authority (EFSA) will carry out the risk assessments. Under the current rules, the Member States’ competent authorities carry out risk assessments and if an objection is raised by a Member State or group of Member States, the Commission asks EFSA for a second evaluation.

**EFSA Risk Assessments:** The new regulation sets out the risk assessment process by EFSA and introduces deadlines.

**EU Positive List:** The new regulation provides for the establishment of Union list of novel foods. Authorizations will be granted through “implementing acts” which means that the European Parliament will not be able to veto them. Authorizations will be generic and no longer applicant-linked. Member States will be able to suspend or temporarily restrict the marketing and use of any novel food in case of an alleged health risk. The Commission will then examine the Member State’s protective measure and take a decision.

**Status:** The new regulation provides for a consultation process when the status of a food or food ingredient is unsure. Procedural steps for the consultation process will be adopted by an implementing act.

**Food from clones:** Until separate legislation on cloning is adopted, food from clones but not offspring will fall within the scope of the Novel Foods Regulation.

**Engineered nanomaterials:** Engineered nanomaterials require a novel food authorization before being used in food. The definition currently set out in the Food Information to Consumers Regulation 1169/2011 is transferred to the new Novel Foods Regulation.

**Traditional food from third countries:** Traditional foods from third countries with a demonstrated safe history of use of at least 25 years would only need to be notified if no safety concerns are raised by Member States or EFSA.

**U.S. Exporters are advised to check the legal status of novel food ingredients**

## **B. Food from Animal Clones**

<http://www.usda-eu.org/topics/animal-cloning/>

Food derived from cloned animals currently falls within the scope of the [Novel Food Regulation 258/97](#). Under this regulation, food produced by “new breeding practices” needs a pre-market approval based on a risk assessment. In December 2013, under pressure of the European Parliament and the Council of the EU, the European Commission proposed two pieces of specific legislation on food from cloned animals: 1) a [proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes](#) and 2) [a proposal to prohibit the placing on the market of food from animal clones](#). The discussion on the cloning proposals between the European Parliament and the Council of the EU is ongoing. Until separate legislation is adopted, food from clones falls within the scope of the Novel Foods regulation.

## **C. Nanotechnology**

<http://www.usda-eu.org/topics/nanotechnology/>

Currently, EU legislation that explicitly addresses nanomaterials in food includes the following regulations:

**Food Information to Consumers (FIC):** [Regulation 1169/2011](#) defines engineered nanomaterials as “any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale”. The current definition uses size as the only defining criterion and does not include a threshold value. The presence of engineered nanomaterials in food products must be clearly indicated on the label. The name of such ingredients must be followed by the word “nano” in brackets (Art. 18 of Regulation 1169/2011).

**New Novel Foods Regulation:** The definition of engineered nanomaterials is set out in the new Novel Foods Regulation (see point A) and will be deleted from the FIC Regulation (applicable end 2017).

**Food Additives:-** [Regulation 1333/2008](#) states that when “there is a significant change in the production methods or in the starting materials used” for food additives already on the Community list of approved food additives, “or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market”.

**Food Contact materials –** [Regulation 450/2009](#) on active and intelligent packaging states that “new technologies to engineer substances with different chemical and physical properties than the same substances at a larger scale, for example nanoparticles, should be assessed at a case-by-case basis as regards their risk until more information is known about such new technology”.

For more information on nanotechnology in the EU see:

- FoodDrinkEurope: <http://www.fooddrinkEurope.eu/our-actions/topic/nanotechnology/eu-projects/>
- European Food Safety Authority: <http://www.efsa.europa.eu/en/supporting/pub/762e>
- [European Commission Joint Research Center](#)

## D. Fortified Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/fortified-foods/>

[European Parliament and Council Regulation 1925/2006](#) established an EU-wide regulatory framework for the addition of vitamins and mineral and of certain other substances such as herbal extracts to foods. It lists the vitamins and minerals that may be added to foods and sets criteria for setting maximum and minimum levels. A European Commission proposal setting harmonized maximum and minimum permitted levels of vitamins and minerals in foods and food supplements is already seven years overdue (original deadline set by Regulation 1925/2006 was January 2009). Vitamins and minerals must be expressed as a percentage of the “Reference Intakes” listed in Annex III to the [“Food Information to Consumers” regulation 1169/2011](#) (see also Section V “Nutrition Declaration”. The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed. A “Community Register” on the addition of vitamins and minerals and of certain other substances is available on the European Commission’s website at [http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm\\_reg\\_en.pdf](http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf).

**Maximum permitted levels of vitamins and minerals in foods and food supplements are not yet EU harmonized**

## E. Dietetic Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/dietetic-foods/>

In June 2013, the EU adopted [Regulation 609/2013](#) which completely overhauls the current dietetic food rules (see Section V “Special Use Foods”). The scope of this regulation is limited to infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and

total diet replacement for weight control. Regulation 609/2013 will apply as of July 20, 2016. Under the new rules, pictures of infants will no longer be allowed on labels. Foods that no longer fall within the scope of Regulation 609/2013 will be regarded as regular foods.

The European Food Safety Authority (EFSA) has published scientific and technical guidance to help the European Commission apply new rules on foods for special medical purposes (FSMPs). For more information see [EFSA'S FAQ document on FSMPs](#).

Regulation 609/2013 also requires the Commission to prepare a report on introducing harmonized rules on food intended for sportspeople. In order to comply with this requirement, the Commission has requested EFSA to provide scientific assistance. For more information see [EFSA's technical report](#).

## **F. Irradiated Foodstuffs**

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval. [Framework Directive 1999/2/EC](#) outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods or foods containing irradiated ingredients must be labeled "irradiated" or "treated with ionizing radiation". For more information see the European Commission's website at [http://ec.europa.eu/food/food/biosafety/irradiation/comm\\_legisl\\_en.htm](http://ec.europa.eu/food/food/biosafety/irradiation/comm_legisl_en.htm).

## **G. Seafood**

Detailed information on shipping seafood and fishery products to the EU is provided in the exporter guide "Exporting Seafood to the European Union – August 2015 Update" which can be downloaded from the Department of Commerce – NOAA Fisheries' website at <http://www.seafood.nmfs.noaa.gov/pdfs/howtoexportseafood2015.pdf>. Information on labeling can also be found in the European Commission's "[Pocket Guide to the EU's new fish and aquaculture consumer labels](#)", published in December 2014.

## **H. Pet Food**

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/pet-food/>

In the EU, pet food is subject to feed marketing legislation and veterinary legislation. The EU's feed marketing legislation covers food for pets as well as feed for food-producing animals. The veterinary legislation covers products of animal origin and hay/straw as these products present a risk for spreading animal diseases. Pet food products containing an animal origin ingredient must be sourced from approved establishments and have to be accompanied by a veterinary certificate. All exports of U.S. pet food to the EU must comply with EU requirements including rules on labeling, hygiene, animal health, certification and the use of additives. [GAIN report "Exporting Pet Food to the European Union"](#) provides a detailed overview of EU legislation relating to imports of pet food.

[European Parliament and Council Regulation 767/2009](#) sets out rules for the labeling and marketing of

feed and pet food. It covers feed materials, compound feed and medicated or dietetic feed for both food and non-food producing animals. For more information see [GAIN report E50060 “EU Feed and Pet Food Labeling Requirements”](#). Feed and pet food not complying with Regulation 767/2009 and with the provisions on feed additives laid down in [Regulation 1831/2003](#) will not be allowed on the EU market. Conditions for mixing veterinary medicine into feed are set out in [Directive 90/167/EEC](#). In September 2014, the European Commission presented a proposal to replace the outdated Directive 90/167/EEC on medicated feed. The scope of the proposal explicitly includes medicated feed for pets. Adoption of this proposal is expected in the first half of 2016. EU border inspection officials will verify the labels on imported pet food for compliance with EU requirements. Annex 4 to the [“Code of Good Labeling Practice for Pet Food”](#), drafted by the European Pet Food Industry (FEDIAF) establishes a “check-list” that pet food manufacturers can use to verify compliance with EU labeling rules.

[Commission Regulation 68/2013](#) establishes a catalogue of feed materials. It enables operators to use more precise names and expressions for the feed they place on the market. The annex to the Catalogue contains three parts: A) general provision, B) glossary of processes and C) list of feed materials. The use of the Catalog is voluntary but where it is used all relevant provisions have to be complied with.

[Commission Recommendation 2011/25/EU](#) establishes guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.

## Section VII. Facility and Product Registration

### A. Facility Registration

The EU approves establishments to ship products of animal origin based on submissions from U.S. government agencies. Only products processed in approved establishments may enter the EU. Detailed information on approved U.S. establishments is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>. Third country lists per sector and per country are published on the European Commission’s website [http://ec.europa.eu/food/food/biosafety/establishments/third\\_country/index\\_en.htm](http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm).

### B. Product Registration

U.S. exporters should be aware that certain products and ingredients may fall within the scope of the Novel Foods Regulation and need a pre-market authorization. Detailed information is provided in Section VI “Other Specific Standards”.

The introduction of **foodstuffs with particular nutritional uses** needs to be notified to the Member State where the food is sold. Exporters of **vitamin-enriched foods** or **nutritional supplements** are especially advised to check for the existence of specific Member State registration or notification requirements. A list of the competent Member State authorities is available on the European Commission’s website at [http://ec.europa.eu/food/food/labellingnutrition/supplements/food\\_supplements\\_authorities.pdf](http://ec.europa.eu/food/food/labellingnutrition/supplements/food_supplements_authorities.pdf).



## Section VIII. Other Certification and Testing Requirements

### Certification and Documentation Requirements

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>

An overview of legally required certificates in the EU and references to the U.S. authority issuing these certificates is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

**Composite Products:** U.S. exports of “composite products” are continuing to be restricted due to burdensome certification requirements introduced in a 2012 European Commission Regulation. Composite products are defined as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin. Composite products include a wide variety of products, including cheesecakes, high protein food supplements, pizza, and lasagnas. While the U.S. is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often no longer possible to ship the composite products that combine these eligible ingredients.

All composite products containing a processed meat product are subject to a veterinary check. Generally speaking, composite products that contain more than 50 of animal origin products also require a certificate, and there are certification requirements concerning the heat treatment for all dairy products. The EU has created a model health certificate for imports of composite products, which was implemented in 2012. [A detailed Product Decision Tree to clarify the scope of the legislation was published in 2013.](#) This guidance greatly expanded the number and types of products affected by the legislation. [Further guidance](#) was developed and published in 2015 to address a wide range of implementation questions related to the import and transit of composite products. For more information see <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

### Inspections

Member State authorities are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. Infringements of EU food and feed legislation are reported through the Rapid Alert System on Food and Feeds (RASFF). The rapid alert system is a network of Member State authorities managed by the European Commission. The weekly reports of the notifications under the rapid alert are available on the European Commission’s website ([http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)). The information published on the website is limited to the notifying country, the reason for notifying and the country of origin. Repeated non-compliance may lead to suspension of imports or special import conditions for products from the third country concerned, applicable on the entire EU territory.

Criteria for laboratories conducting food controls have been harmonized but it is the Member States’ responsibility to designate laboratories that are allowed to perform analyses.



Specific detailed inspection requirements exist for animal products ([Directive 97/78/EC](#)). Products of animal origin must be presented at a Community border inspection post and submitted to an import control following prior notification of the shipment. [Commission Decision 2009/821/EC](#) establishes a list of EU border inspection posts approved to carry out veterinary checks on animals and animal products from third countries. [Commission Decision 2007/275/EC](#) establishes a list of animals and products that are subject to controls at border inspection posts, including certain composite products as well as a list of composite products that are not subject to veterinary checks.

[European Parliament and Council Regulation 854/2004](#) lays down specific rules for the organization of official controls on products of animal origin. [European Parliament and Council Regulation 882/2004](#) lays down general rules for the performance of official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. [Commission Regulation 669/2009](#) implements Regulation 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described on <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

Inspection fees for non-animal origin products differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

An overview of sanitary and phytosanitary requirements is also available on the European Commission websites: DG Health and Consumers [“International Affairs – Import Conditions”](#) and DG Trade [“Export Helpdesk”](#).

## **Section IX. Import Procedures**

### **A. Union Customs Code**

On May 1, 2016, the new “Union Customs Code” established in [European Parliament and Council Regulation 952/2013](#) becomes applicable. Until then, the current Community Customs Code ([Council Regulation 2913/92](#)) and its implementing provisions continue to apply.

The Code lists all the customs procedures applicable to the trade in goods with third countries. Import duties are determined by the tariff classification of goods and by the customs value. With the implementation of the Code, the Member States of the European Union form a customs union which means that all the Member States apply the same tariff on goods imported from outside the EU. Once an imported good is cleared in one Member State, it can move freely throughout the EU.

All traders involved in customs transactions have to provide EU customs authorities with security data on

goods before they are imported into the EU. The type of security data requested varies according to the means of transport and can include a description of the goods, information on the consignor or exporter, the route of the goods and any potential hazards. The time limits for submitting advance security data also vary according to the means of transport: 24 hours for maritime cargo to 1 hour for road traffic and air transport.

A complete overview of the EU's customs policy issues is available on the European Commission's [DG for Taxation and Customs Union website](#).

## B. Customs Clearance

The European Commission's DG Trade "Export Helpdesk" provides a complete overview of documents needed for customs clearance:

[http://exporthelp.europa.eu/thdapp/display.htm?page=rt%2ft\\_Requirements.html&docType=main&languageId=en](http://exporthelp.europa.eu/thdapp/display.htm?page=rt%2ft_Requirements.html&docType=main&languageId=en)

## C. Import Duties

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight digit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings; the two following digits represent the CN subheadings. The EU's [on-line "Taric" customs database](#) can be consulted to look up commodity codes and relevant import duties. Taric is a multilingual database covering all measures relating to tariff and trade legislation. The [EU's 2016 Tariff Schedule](#) was published on October 30, 2015 in Official Journal L 285. A list of Member State customs authorities can be found at

[http://ec.europa.eu/taxation\\_customs/customs/procedural\\_aspects/general/national\\_contacts/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/procedural_aspects/general/national_contacts/index_en.htm).

It is also possible to obtain Binding Tariff Information (BTI) from a member state's customs authority to get the proper product classification. Through this system, traders know in advance the tariff classification of the goods they intend to import. BTI, generally valid for six years, is legally binding in all the member states. Information on how to obtain a BTI can be downloaded from DG Taxation & Custom's website at

[http://ec.europa.eu/taxation\\_customs/customs/customs\\_duties/tariff\\_aspects/classification\\_goods/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/classification_goods/index_en.htm). A [list of customs authorities designated for the purpose of issuing binding tariff information](#) was published in Official Journal C 261 of August 8, 2015. All BTIs issued by the national customs authorities have been entered into the European Commission's [EBTI-database](#). The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

[Commission Regulation 900/2008](#) lays down analytical methods and other technical provisions to calculate the starch/glucose and sucrose/invert sugar/isoglucose content in processed products. These calculations are used to determine the additional duties on flour and sugar in processed products. Goods are only released after payment of the import duty and other taxes that may be due. Duties payable on goods imported into the EU may include:

- import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces) – EU harmonized
- additional duties on flour and sugar (processed products) – EU harmonized
- entry price (fruit and vegetables) – EU harmonized
- environmental taxes - not harmonized
- inspection fees - not harmonized
- Value Added Tax (VAT) - not harmonized
- excise duties (alcohol and tobacco) - not harmonized

A list of VAT rates applicable in the different Member States can be found on the Internet at [http://ec.europa.eu/taxation\\_customs/resources/documents/taxation/vat/how\\_vat\\_works/rates/vat\\_rates\\_en.pdf](http://ec.europa.eu/taxation_customs/resources/documents/taxation/vat/how_vat_works/rates/vat_rates_en.pdf).

A list of excise duties applicable on alcoholic beverages and tobacco can be found at [http://ec.europa.eu/taxation\\_customs/taxation/excise\\_duties/index\\_en.htm](http://ec.europa.eu/taxation_customs/taxation/excise_duties/index_en.htm).

Other customs procedures described in detail in the EU Customs Code include entry into free zones, situations where no import duty is payable: e.g. the inward processing regime, under which goods can be imported for processing but the finished product must be exported from the Community market. The Code also provides for a two-stage right of appeal lodged in the Member State where a decision has been taken or applied for: in the first instance to the customs authority, then to the national courts.

**For detailed information see also the  
European Commission's "Export Helpdesk"**

## **Section X. Copyright and/or Trademark Laws**

### **A. Trademarks**

There are two ways to register a trade mark in the EU. A trade mark can either be registered at national level at the industrial property office of EU Member States or at EU-level as a "Community trade mark" at the [Office for Harmonization in the Internal Market](#). A Community Trade Mark gives the owner protection in all EU Member States with one single registration. The website of the Office for

Harmonization in the Internal Market provides detailed information on the definition, registration process and ownership of trade marks: <https://oami.europa.eu/ohimportal/en/trade-marks>. Information on EU trade mark protection criteria can be found on the European Commission's website at [http://ec.europa.eu/growth/industry/intellectual-property/trade-mark-protection/index\\_en.htm](http://ec.europa.eu/growth/industry/intellectual-property/trade-mark-protection/index_en.htm).

## **B. Protected Geographical Indications**

<http://www.usda-eu.org/topics/geographical-indications/>

Several food product names considered as generic in the U.S. such as for example feta, parmesan and Parma ham, are protected under EU law. [European Parliament and Council Regulation 1151/2012](#) sets out rules on optional quality terms such as “mountain product” and regulates three EU-wide quality labeling schemes. It covers the “Protected Designation of Origin” (PDO) scheme, the “Protected Geographical Indication” (PGI) scheme and the “Traditional Specialties Guaranteed” (TSG) scheme. Registration under the different schemes is open to third countries. Wines and spirits are covered by specific legislation and do not fall within the scope of the regulation.

The provisions on labeling and the use of EU logos for PDOs, PGIs and TSGs set out in Regulation 1151/2012 become applicable on January 4, 2016. The [European Commission's website](#) provides guidance on how to register a PDO/PGI or how to object to a PDO/PGI proposed for registration. Lists of protected names by country, product type, registered name and name applied for are available through the Commission's [online “DOOR” \(Database of Origin and Registration\) database](#).

**“Protected Designation of Origin” (PDO)** is defined as follows:

- Originating in a specific place, region or in exceptional cases, a country
- Quality and characteristics of the product are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors
- ALL of the production steps take place in the defined geographical area

Example of a PDO: Prosciutto di Parma (Parma ham)

**“Protected Geographical Indication” (PGI)** is defined as follows:

- Originating in a specific place, region or country
- Quality, reputation or other characteristics are essentially attributable to the geographical origin
- At least one of the production steps takes place in the defined geographical area

Example of a PGI: Gouda Holland

**“Traditional Specialties Guaranteed” (TSG):**

The TSG quality label is used to communicate the value-added characteristics of traditional recipes and

traditional production methods to consumers. “Traditional” is defined as a proven usage of at least 30 years. Unlike the PDO and PGI schemes, the geographical origin of a product is irrelevant under the TSG scheme. Under the new rules, TSGs are included a Community Register with name reservation. Only products complying with the TSG specifications can use the registered name.

Example of a TSG: Mozzarella

Detailed information on the TSG scheme is available in [GAIN report E80061 “The EU’s Traditional Specialties Guaranteed” Scheme Explained](#)”.

### **Optional Quality Terms:**

Regulation 1151/2012 sets out criteria for the use of optional quality terms. The European Commission is empowered to reserve new terms or amend the conditions of use of existing terms.

Example of an optional quality term: Mountain Product

**Regulation 1151/2012 on EU Quality Schemes becomes applicable on  
January 4, 2016**

## **APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS**

European Commission  
Rue de la Loi 200  
1049 Brussels  
Belgium  
Tel: (32-2) 299 1111

Office for Harmonization in the Internal Market  
Avenida de Aguilera, 20  
03080 Alicante  
Spain  
Tel: (34-96) 513 9243  
Fax: (34-96) 513 9173

European Union - Delegation of the European Commission to the United States  
2300 M Street  
NW, Washington, DC 20037  
Tel: (202) 862-9500  
Fax: (202) 429-1766

United States Mission to the European Union  
Office of Agricultural Affairs  
Mailing address:  
27 Boulevard du Regent  
1000 Brussels  
Belgium  
Tel: (32-2)811-5793  
Fax: (32) (2) 811-5560  
E-mail: [AgUSEUBrussels@fas.usda.gov](mailto:AgUSEUBrussels@fas.usda.gov)  
Website: [www.usda-eu.org](http://www.usda-eu.org)

National Oceanic & Atmospheric Administration (NOAA) Representative to the EU:  
Mailing address:  
27 Boulevard du Regent  
1000 Brussels  
Belgium  
Tel: (32-2)811-5831  
E-mail: [Stephane.Vrignaud@trade.gov](mailto:Stephane.Vrignaud@trade.gov)

Food and Drug Administration (FDA)  
Mailing address:  
27 Boulevard du Regent  
1000 Brussels  
Belgium  
Tel: (32-2)8114518  
E-mail: [Donald.Prater@fda.hhs.gov](mailto:Donald.Prater@fda.hhs.gov)

Other FAS Offices in the European Union:  
[http://apps.fas.usda.gov/overseas\\_post\\_directory/index.asp](http://apps.fas.usda.gov/overseas_post_directory/index.asp)

FDA contacts for certification of animal products:  
<http://www.fda.gov/AnimalVeterinary/Products/ImportExports/default.htm>

Food Safety & Inspection Service (FSIS) Export Requirements for the EU:  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products>

Animal & Plant Health Inspection Service (APHIS) – Import & Export:  
[http://www.aphis.usda.gov/import\\_export/index.shtml](http://www.aphis.usda.gov/import_export/index.shtml)

## APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS

- Please see [Member States FAIRS reports](#).

### U.S. MISSION TO THE EU – FAS ORGANIZATIONAL CHART

For updates see <http://www.usda-eu.org/contact-fas/>

<b>James Higgiston, Minister-Counselor for Agricultural Affairs</b>		
<b>Mary Ellen Smith Senior Agricultural Attache</b>	<b>Marcela Rondon Agricultural Attache</b>	<b>Karisha Kuypers Agricultural Attache</b>
T-TIP EU Food & Agriculture Policies CSS Budget & Administration ICASS	Biotechnology New Breeding Techniques Nanotechnology Grains & Feed Oilseeds & Products Organic Products Biofuels Sugar Forest Products Biofuels Food & Feed Additives Packaging Materials Sustainability / Climate Change Wines & Spirits WTO Bilateral Coverage (Belgium)	Dairy, Livestock & Poultry Veterinary Equivalency Agreement Pathogen Reduction Treatments Animal Health Animal Cloning GE Animals Animal Products Novel Foods Pet Food Food & Drink Labeling Geographical Indications Fish & Seafood Horticultural Products Endocrine Disruptors Pesticides/Contaminants CSSF
<b>LOCAL STAFF</b>		
<b>Gerda Vandercammen Agricultural Specialist</b>	<b>Vacant Agricultural Specialist</b>	<b>Yvan Polet Agricultural Specialist</b>
EU Food & Feed Import Controls EU General Food Law / Food Hygiene EU Food Safety Policies Contaminants Certification/TRACES Risk Analysis CODEX Bilateral Port Issues (Belgium)	Oilseeds & Products Biofuels Sustainability/Climate Change/Environment Organic Products Rural Development Forest Products	Dairy, Livestock & Poultry Animal Welfare Animal Health Animal Cloning GE Animals WTO (Market Access, Domestic Support, Export Competition) Sugar
<b>Barrie Williams Agricultural Specialist</b>	<b>Tania De Belder Agricultural Specialist</b>	<b>Hilde Brans Agricultural Specialist</b>
Biotechnology CAP Grains & Feed EU Budget Risk Analysis	Biotechnology New Breeding Techniques Pesticides Food & Feed Additives Nanotechnology Packaging Materials Horticultural Products WTO SPS & TBT Notifications	EU Decision-Making Procedures Food & Drink (Incl. Wine & Spirits) Labeling Nutrition & Health Claims Novel Foods Animal Cloning Dietetic Foods & Food Supplements EU Food Quality Schemes Pet Food
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